DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 19, 2015

Monteris Medical, Inc.
% Mr. Craig Coombs
President
Coombs Medical Device Consulting
1193 Sherman Street
Alameda, California 94501

Re: K143457
Trade/Device Name: Neuroblate System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 19, 2015
Received: January 21, 2015

Dear Mr. Craig Coombs,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143457

Device Name
Monteris Medical NeuroBlate™ System

Indications for Use *(Describe)*
The Monteris Medical NeuroBlate™ System is indicated for use to ablate, necrotize, or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers.

The Monteris Medical NeuroBlate™ System is intended for planning and monitoring thermal therapies under MRI visualization. It provides MRI based trajectory planning assistance for the stereotaxic placement of MRI compatible (conditional) NeuroBlate™ Laser Delivery Probes. It also provides real time thermographic analysis of selected MRI images.

When interpreted by a trained physician, this System provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of the NeuroBlate™ System analysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary
K143457

a. Device Information:

Category	Comments
Sponsor:	Monteris Medical Corp. 16305 36th Ave. North, Suite 200 Plymouth, MN 55446 763-253-4710 Fax: 763-746-0084 www.monteris.com
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Magnetic Resonance Image Guided Laser Thermal Therapy System
Device Classification Number:	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 882.4560 Stereotaxic instrument
Device Classification & Product Code:	Class II, GEX Class II, HAW
Device Proprietary Name:	Monteris Medical NeuroBlate™ System

Predicate Device Information:

Predicate Device:	NeuroBlate™ System
Predicate Device Manufacturer:	Monteris Medical
Predicate Device Common Name:	Monteris NeuroBlate™ System
Predicate Device Premarket Notification #	K141983
Predicate Device Regulation:	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 882.4560 Stereotaxic instrument
Predicate Device Classification & Product Code:	Class II, GEX Class II, HAW

b. Date Summary Prepared
19 February 2015

c. Description of Device

The Monteris NeuroBlate™ System is a collection of MRI-compatible laser devices and accessories that create an MRI guided delivery of precision thermal therapy in the practice of neurosurgery.

The NeuroBlate System components consist of:

- Families of gas-cooled Laser Delivery Probes (Probe) (SideFire & FullFire) to deliver controlled energy to a target zone. This application includes the smaller diameter SideFire Select and FullFire Select families of Probes;
- Probe Drivers (Advanced Probe Driver, Robotic Probe Driver) which allow the surgeon to precisely position, stabilize and manipulate a probe, endoscope or other device within the target zone.
- An Interface Platform, which attaches to the MRI system patient table and provides supporting electronics for the Probe Drivers and interconnections for the Laser Delivery Probes;
- A System Electronics Rack and Components, which includes necessary umbilicals, cables, penetration panels, and small hardware for system mechanical, electrical, and electronic operation, and
- A Control Workstation including the *M-Vision*™ software, which includes a user interface for procedure planning, interactive monitoring of NeuroBlate™ procedures, and interfaces to the MRI and hardware subsystems.

This submission adds a line of 2.2mm Reduced Diameter Probes to the existing 3.3mm diameter probes. They will be known as the SideFire Select™ and FullFire Select™ Probes.

d. Indications for Use

The Monteris Medical NeuroBlate™ System is indicated for use to ablate, necrotize, or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers.

The Monteris Medical NeuroBlate™ System is intended for planning and monitoring thermal therapies under MRI visualization. It provides MRI based trajectory planning assistance for the stereotaxic placement of MRI compatible (conditional) NeuroBlate™ Laser Delivery Probes. It also provides real-time thermographic analysis of selected MRI images.

When interpreted by a trained physician, this System provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of the NeuroBlate™ System analysis.

e. Comparison to Predicate Device

The application Monteris Medical NeuroBlate™ System with the Reduced Diameter Laser Delivery Probes is substantially equivalent to the predicate Monteris NeuroBlate™ System (K141983) in intended use, technology, design and physician use.

The Indications for Use for the modified NeuroBlate System are unchanged from the predicate NeuroBlate System. The fundamental technology is also unchanged.

All patient contacting materials are identical in composition, source, and use with respect to the predicate device.

The technical modes of action and technical principles are materially the same as the predicate devices.

The application System with the Reduced Diameter Laser Delivery Probes has similar laser emission patterns and laser ablation effect as the predicate Laser Delivery Probes. The expected use of the Reduced Diameter Probe for either its SideFire or FullFire is no different than the expected use of the predicate laser delivery probes.

Bench testing has demonstrated that the System is in compliance with the medical community's expectations and the product labeling and specifications. It demonstrates that NeuroBlate system works as well with the Reduced Diameter Probe as it does with the larger diameter versions.

As the modifications presented in the current device do not change the intended use, operating principles, or raise any unaddressed safety concerns, it can be concluded the application NeuroBlate™ System with the added Reduced Diameter Laser Delivery Probes is substantially equivalent to the predicate NeuroBlate™ System.

f. Summary of Supporting Data

Bench verification testing has demonstrated that the NeuroBlate System in general, and the new sizes of Laser Delivery Probes in particular, are in compliance with the medical community's expectations and the product labeling and product specifications.

In particular, the bench testing demonstrated that the new sizes of the Laser Delivery Probes exhibited compliance to the same electrical requirements, mechanical integrity and operation (e.g., cooling) requirements, and laser emission requirements as the predicate sizes; that they interfaced with the NeuroBlate System in an identical manner; and that adequate labeling information was provided to ensure that they could be accurately placed within the target tissue.